

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

KRIWET ET AL.

APPLICATION NO:

FILED:

FOR: TOPICAL COMPOSITIONS COMPRISING ASCOMYCINS

Assistant Commissioner for Patents  
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

IN THE SPECIFICATION

Please amend the Specification as follows:

Under the Title, please insert

-- This is a continuation of International Application No. PCT/EP99/09351, filed December 1, 1999, the contents of which are incorporated herein by reference. --

IN THE CLAIMS

Please cancel claims 1-13 and add the following new claims:

14. (new) A composition for topical administration of an ascomycin for treatment of skin disorders which composition comprises a carrier vehicle comprising
  - (i) means to retain water in the outer skin layer comprising a urea, an inorganic salt, or a carboxylic acid, and
  - (ii) means to hinder water evaporating from the skin.
15. (new) A composition for topical administration of 33-epi-chloro-33-desoxy-ascomycin which composition comprises a carrier vehicle comprising
  - (i) means to retain water in the outer skin layer, and

(ii) means to hinder water evaporating from the skin.

16. (new) A composition as claimed in claim 14 wherein the means to retain water in the outer skin layer is an inorganic salt.

17. (new) A composition as claimed in claim 15 wherein the means to retain water in the outer skin layer is an inorganic salt.

18. (new) A composition as claimed in claim 14 wherein the means to hinder water evaporating from the skin is a hydrocarbon.

19. (new) A composition as claimed in claim 15 wherein the means to hinder water evaporating from the skin is a hydrocarbon.

20. (new) A composition as claimed in claim 16 wherein the means to hinder water evaporating from the skin is a hydrocarbon.

21. (new) A composition as claimed in claim 18 wherein the hydrocarbon comprises petrolatum, liquid paraffin, microcrystalline wax, solid paraffin, or a reaction product of paraffin and polyethylene.

22. (new) A composition as claimed in claim 19 wherein the hydrocarbon comprises petrolatum, liquid paraffin, microcrystalline wax, solid paraffin, or a reaction product of paraffin and polyethylene.

23. (new) A composition as claimed in claim 14 wherein the carrier vehicle further comprises

(iii) liquid means to solubilize ascomycin.

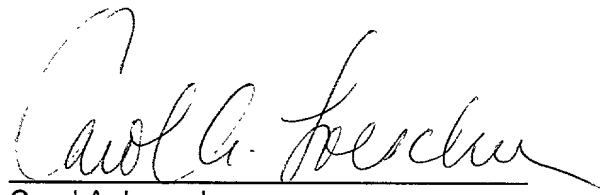
24. (new) A composition as claimed in claim 15 wherein the carrier vehicle further comprises

(iii) liquid means to solubilize 33-epi-chloro-33-desoxy-ascomycin.

25. (new) A composition as claimed in claim 23 wherein the liquid means comprises a wax, a fatty alcohol, a fatty acid, or fatty oil.
26. (new) A composition as claimed in claim 24 wherein the liquid means comprises a wax, a fatty alcohol, a fatty acid, or a fatty oil.
27. (new) A composition as claimed in claim 25 wherein the liquid means is isopropyl myristate.
28. (new) A composition as claimed in claim 26 wherein the liquid means is isopropyl myristate.
29. (new) A composition as claimed in claim 14 wherein the ascomycin is present in an amount of 0.1 to 2.0 % by weight of the composition.
30. (new) A composition as claimed in claim 15 wherein the 33-epi-chloro-33-desoxy-ascomycin is present in an amount of 0.1 to 2.0 % by weight of the composition.
31. (new) A composition as claimed in claim 14 wherein the means to retain water in the outer skin layer is present in an amount of 0.1 to 20% by weight of the composition.
32. (new) A composition as claimed in claim 15 wherein the means to retain water in the outer skin layer is present in an amount of 0.1 to 20% by weight of the composition.
33. (new) A method for enhancing penetration of an ascomycin through human skin comprising administering a composition according to claim 14 to said human skin.
34. (new) A method for enhancing penetration of 33-epi-chloro-33-desoxy-ascomycin through human skin comprising administering a composition according to claim 15 to said human skin.
35. (new) A method of treatment to an inflammatory or hyperproliferative skin disease comprising administering to skin of a patient in need of such treatment a composition according to claim 14.

36. (new) A method of treatment to an inflammatory or hyperproliferative skin disease comprising administering to skin of a patient in need of such treatment a composition according to claim 15.
37. (new) A method of treatment of cutaneous manifestations of immunologically mediated diseases comprising administering to skin of a patient in need of such treatment a composition according to claim 14.
38. (new) A method of treatment of cutaneous manifestations of immunologically mediated diseases comprising administering to skin of a patient in need of such treatment a composition according to claim 15.

Respectfully submitted,



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